IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE HONORABLE BOARD OF PATENT APPEALS AND INTERFERENCES

APPEAL BRIEF

Ex parte Kazuhisa MATSUDA

SUTURABLE ADHESION-PREVENTING MEMBRANE

App. No	:	09/489,473
Filed	:	January 21, 2000
TC/A.U.	:	1771
Examiner	:	C. C. Pratt

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Date: March 17, 2004

Atty. Docket No. NISS-049

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Appl. No. : 09/489,473 Confirmation No. 5891

Applicant : Kazuhisa MATSUDA

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Dkt. No. : NISS-049

Cust. No. : 20374

BRIEF ON APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450 March 17, 2004

Sir:

This is an appeal from the decision dated July 16, 2003, of the primary Examiner finally rejecting claims 1-33 in this application.

(1) REAL PARTY IN INTEREST

The real party in interest is NIPRO CORPORATION of 9-3, Honjo-nishi 3-chome, Kita-ku, Osaka-shi, Osaka-fu, 531-8510, Japan.

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

(3) STATUS OF CLAIMS

Claims 1-14 are pending in this application. Claims 15-33 have been cancelled. Claims 1-15 are appealed. Claims 1-14 as finally rejected are set forth in the attached Appendix.

(4) STATUS OF AMENDMENTS

An amendment canceling claims 15-33 was filed subsequent to the final rejection.

(5) SUMMARY OF INVENTION

The present invention is a suturable adhesion-preventing membrane for guided tissue regeneration that is used for repairing, augmenting or replacing parts of tissues and organs such as an abdominal wall, pleura, pericardium, cerebral dura mater and chorion. (Page 1, lines 2-13).

The suturable adhesion-preventing membrane of the present invention comprises at least one non-woven fabric made of collagen fibers and at least one sponge layer made of collagen, and a coating layer of gelatin or hyaluronic acid on at least one of the surfaces of the membrane. (Page 6, lines 11-20).

The suturable adhesion-preventing membrane for guided tissue regeneration of the present invention can concurrently provide an

adhesion-preventing effect, mechanical strength capable of suture fixation, biocompatibility and guiding tissue regeneration. (Page 5, line 21, to page 6, line 9).

Prior to the present invention, conventional adhesion-preventing membranes could not resolve simultaneously the problems of insufficient suture strength, insufficient biocompatibility or decomposition and absorption capability in a living body and insufficient adhesion-preventing effects. (Page 3, lines 15-20). Such conventional membranes include a surgical wound dressing material in which a non-woven fabric layer made of collagen fibers is treated with aldehydes as a cross-linking agent to provide water resistance and the fibers are bonded mutually with collagen (page 3, lines 3-13) and a medical collagen membrane of non-woven fabric layer which comprises cross-linked collagen in which at least one surface of the membrane is covered with a collagen coating (page 4, line 3, to page 5, line 18).

(6) ISSUES

The following issues are raised by the final rejection:

(1) whether the combination of Light et al., U.S. Patent No. 5,514,181 (hereinafter: "Light") and Silver et al., U.S. Patent No. 5,171,273 (hereinafter: "Silver") relied on by the Examiner is

sufficient to support a case of *prima facie* obviousness under 35 U.S.C. § 103(a) of the suturable adhesion-preventing membrane for guided tissue regeneration recited in claims 1-14; and

(2) whether the modification of the prosthesis of Light proposed by the Examiner will result in a suturable adhesion-preventing membrane for guided tissue regeneration as recited in claims 1-14.

(7) GROUPING OF CLAIMS

Claims 1-14 stand or fall together.

(8) ARGUMENT

(a) Light Teaches Away from the Present Invention

Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under § 103 requires, inter alia, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of

success. *See In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure. *Id.*

The first factor has been interpreted as a requirement for a suggestion, teaching, or motivation to combine the prior art references. *See C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232(Fed. Cir. 1998). Evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness is required. *See, e.g., McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351-52, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001). The showing of the requisite suggestion or motivation must be specific. *See, e.g., In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) ("particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed"). (Emphasis added).

In the present case, the Examiner has not provided a proper showing of why the art-skilled person, without knowledge of the present application, would have combined the teachings of Light and

Silver as he has proposed, particularly when the disclosure of Light as a whole is considered (as it must under 35 U.S.C. § 103(a)).

Light discloses a bioabsorbable ligament or tendon prothesis described as "comprising the following spiral layers: a foraminous layer of a synthetic bioabsorbable material; a bioabsorbable film, and a layer of a bioabsorbable sponge." (Col. 2, lines 46-50). (Emphasis added). Silver, as described in Col. 1, lines 58-67, of Light, discloses absorbable ligament or tendon protheses formed from high-strength collagen fibers.

The Examiner's position in the Final Rejection, and as stated in the Office Action dated November 6, 2002, is that a person of ordinary skill in the art would have been motivated to use the collagen fibers disclosed in Silver to form the foraminous layer of a synthetic bioabsorbable material of the bioabsorbable ligament or tendon prothesis of Light.

Light, itself, however, teaches away from the use of the collagen fibers of Silver in the ligament or tendon prothesis of the invention disclosed therein. Specifically, as noted above, Light describes Silver in the "Background of the Invention" section thereof (Col. 1, lines 58-67) as disclosing absorbable ligament or tendon prostheses formed from high-strength collagen fibers that

are obtained by cross-linking reconstituted collagen fibers. In the paragraph preceding the description of Silver, WO85/00511 is described as disclosing a collagen-based material for regeneration of ligaments and/or tendons. The material is described as being formed from strands of collagen that have been cross-linked with glutaraldehyde to increase their tensile strength. Light then indicates that the protheses of Silver and WO85/00511 are disadvantageous. Light describes:

> "A drawback of tendon and/or ligament prostheses that are formed solely from collagen is that the collagen loses its tensile strength in vivo, even when cross-linked as described above. This characteristic of collagen is incompatible with the relatively long healing times required for repair of ligaments or tendons."

(Col. 2, lines 1-6). (Emphasis added).

Light then describes that absorbable prostheses based solely on synthetic, non-collagenous polymers, i.e., "a synthetic bioabsorbable polymer, such as a copolymer of lactic and glycolic acids, polyhydroxy butyric acid, or the like" (Col. 2, lines 15-17) (emphasis added) are also disadvantageous because "the prostheses cannot exhibit the beneficial wound-healing properties of biopolymers such as collagen." (Col. 27-30).

In light of (and with obvious awareness of) this prior art, Light discloses that the prosthesis of its invention comprises, as noted above, "a foraminous layer of a synthetic bioabsorbable

material." (Col. 2, lines 48-49) (emphasis added). Light does not describe its invention as a foraminous layer of collagen fibers or a foraminous layer of collagen fibers or a synthetic bioabsorbable material. Nowhere does Light suggest that the foraminous layer can be made of collagen fibers as disclosed in Silver.

When the disclosure of Light as a whole is considered without knowledge of the claimed invention, the motivation alleged in the Action for a person of ordinary skill in the art to use the synthetic collagen fibers of Silver to form the nonwoven layer of Light, i.e., "the desire to obtain high-strength combined with beneficial wound healing properties" (Action, page 3, lines 6-7), does not exist. The only conclusion that a person of ordinary skill in the art could have reasonably drawn from the totality of the disclosure of Light is that the collagen fibers of Silver will not provide the high strength required for a tendon or ligament prosthesis.

Moreover, since the invention of Light was made with obvious knowledge of the Silver patent, Light, if it believed the collagen fibers of Silver or WO88/06872 would not exhibit the drawback described in the patent when used in the Light prosthesis, would have described such fibers as being useful. The fact that Light does not disclose the collagen fibers of Silver or WO88/06872 as

being useful for the foraminous layer of its invention is strong evidence showing that the art-skilled person with no knowledge of the claimed invention, would not have been motivation to modify Light with Silver as proposed in the Action.

The Examiner in the Final Action states that the description in Light that prostheses formed "solely from collagen" have a drawback is not germane to the rejection because the prosthesis of Light is not formed solely from collagen. This statement is without logic because the fact that prostheses formed solely from collagen are disadvantageous was considered by Light to be sufficiently germane to its invention to disclose it in the background of its invention. The person of ordinary skill in the art would contrast this disclosure of Light with the invention of Light - not dismiss it.

The Examiner cites the decision of the Federal Circuit in *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (1994) as support for his position that Light does not teach away from the present invention. In *Gurley*, however, the cited reference disclosed that a certain material used in the combination claimed by the appellant was known for use in the same combination albeit with inferior results. In the present case, Light does not disclose that collagen fibers such as those disclosed in Silver were known for

use in a prosthesis comprising a foraminous layer, a film layer and a sponge layer.

Gurley supports the position of the appellant herein that Light teaches away from the invention recited in claims 1-14. In *Gurley* the court noted that "in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant" citing with approval *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966) ("known disadvantages in old devices which would naturally discourage the search for new inventions may be taken into account in determining obviousness"); *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550-51, 220 USPQ 303, 311 (Fed. Cir. 1983) (the totality of a reference's teachings must be considered), cert. denied, 469 U.S. 851 (1984); and *In re Caldwell*, 319 F.2d 254, 256, 138 USPQ 243, 245 (CCPA 1963) (reference teaches away if it leaves the impression that the product would not have the property sought by the applicant). In the present case, the disclosure in Col. 2 of Light regarding the drawback of the use of collagen, when the totality of Light's teachings is properly considered, clearly leaves the impression that the use of collagen in the foraminous layer of the prosthesis of Light will not provide a prosthesis having the

strength required thereof.

For the above reasons, the combination of Light and Silver cannot support a case of *prima facie* obviousness of the suturable adhesion-preventing membrane for guided tissue regeneration of the present invention as recited in claims 1-14 on appeal.

(b) The Proposed Modification of Light Will Not Result in the Suturable Adhesion-preventing Membrane for Guided Tissue Regeneration of the Present Invention.

The invention recited in the claims of the present application is a membrane. The invention of Light is not a membrane, but instead is a prosthesis in the form of a multilayered spiral roll. Light discloses a laminate of a foraminous layer of bioabsorbable material and bioabsorbable film coated with an aqueous gel (Col. 4, lines 47-52). However, the laminate is used only to prepare the prosthesis of Light and is not disclosed as having any utility other than as a raw material for the prosthesis of Light. Moreover, this laminate is not within the scope of the claims of the application because the only description in Light of the formation of the sponge layer is that the sponge layer is formed after the laminate of the foraminous layer of bioabsorbable material and bioabsorbable film coated with the aqueous gel is rolled up into a spiral roll. (See Col. 4, lines 49-51 ("rolling

up the laminate and the gel layer into a spiral roll, followed by drying the gel to form a layer of bioabsorbable sponge") and the examples).

Appellant notes that in the Final Action the Examiner cites Col. 5, lines 30-55, of Light as support for the formation of pores before rolling. The cited disclosure, however, describes only the drying of an aqueous gel used to form the sponge layer as described in Col. 4, lines 49-51, and discloses and suggests nothing concerning the formation of pores prior to rolling. Additionally, although Light illustrates a laminate of a foraminous layer embedded within a sponge layer in Fig. 4, there is nothing to suggest that this laminate is other than one of the multi-layered laminates in the prosthesis or to suggest that the sponge layer of this laminate is formed prior to a foraminous layer embedded within a gel layer being combined with the bioabsorbable polymer film and rolled into a spiral shape and then dried.

Therefore, even if it is assumed for the sake of argument that a person of ordinary skill in the art would be motivated to use the collagen fibers of Silver in the foraminous layer of Light, a membrane as recited in claims 1-14 on appeal will not be obtained.

For this reason also, the 35 U.S.C. § 103(a) rejection is improper.

In view of the foregoing arguments, appellant respectfully requests that the Final Rejection of the Primary Examiner be reviewed and reversed.

Please charge any required fees or credit any overpayment to our Deposit Account No. 111833. This brief is submitted in triplicate.

Respectfully submitted,

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APPENDIX

1. A suturable adhesion-preventing membrane for guided tissue regeneration comprising at least one non-woven fabric layer made of collagen fibers and at least one sponge layer made of collagen, characterized in that a surface of the membrane is provided with a coating layer of gelatin or hyaluronic acid.

2. A suturable adhesion-preventing membrane for guided tissue regeneration according to claim 1, wherein the coating layer containing gelatin or hyaluronic acid is a sponge or film.

3. A suturable adhesion-preventing membrane for guided tissue regeneration according to claim 1, wherein the coating layer containing gelatin or hyaluronic acid comprises cross-linked gelatin or hyaluronic acid.

4. A suturable adhesion-preventing membrane for guided tissue regeneration according to claim 1, wherein the coating layer containing gelatin or hyaluronic acid is formed by lyophilization.

5. A suturable adhesion-preventing membrane for guided tissue regeneration according to claim 1, wherein the coating layer containing gelatin or hyaluronic acid is a compressed sponge layer.

6. A suturable adhesion-preventing membrane for guided

tissue regeneration according to claim 1, wherein the coating layer containing gelatin or hyaluronic acid has a thickness of 0.05 mm to 20 mm.

7. A suturable adhesion-preventing membrane for guided tissue regeneration according to claim 1, wherein the collagen of the collagen fibers and the collagen of the at least one sponge layer are independently selected from enzyme-solubilized collagen, acid-solubilized collagen, alkali-solubilized collagen or neutral solubilized collagen.

8. A suturable adhesion-preventing membrane for guided tissue regeneration according to claim 1, wherein a part or all of the collagen in the non-woven fabric layer made of collagen fibers comprises a cross-linked collagen.

9. A suturable adhesion-preventing membrane for guided tissue regeneration according to claim 1, wherein the non-woven fabric layer made of collagen fibers is obtained by coagulating collagen fibers which are extruded and crossed over in multiple folds, or extruded and wound on a plate in a certain direction to have paralleled lines of fibers, and compressing the coagulated fibers.

10. A suturable adhesion-preventing membrane for guided

tissue regeneration according to claim 1, wherein the non-woven fabric layer made of collagen fibers is a layer in which the fibers are joined together using a binder comprised of solubilized collagen solution.

11. A suturable adhesion-preventing membrane for guided tissue regeneration according to claim 1, wherein the non-woven fabric layer made of collagen fibers has a thickness of 0.05 mm to 100 mm and the coating layer made of gelatin or hyaluronic acid has a thickness of 0.050 mm to 20 mm.

12. A suturable adhesion-preventing membrane for guided tissue regeneration according to claim 1, wherein the membrane is composed of a laminated membranous substance having one to six layers of the non-woven fabric layer made of collagen fibers.

13. A suturable adhesion-preventing membrane for guided tissue regeneration according to claim 1, wherein the collagen non-woven fabric layer has fibers having a fiber diameter of 5 μm to 1.0 mm, and a bulk density (fiber density) of 5×10^{-4} to 5 g/cm^3.

14. A suturable adhesion-preventing membrane for guided tissue regeneration according to claim 1, wherein the overall thickness of the membrane is 0.1 mm to 50 mm.